

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

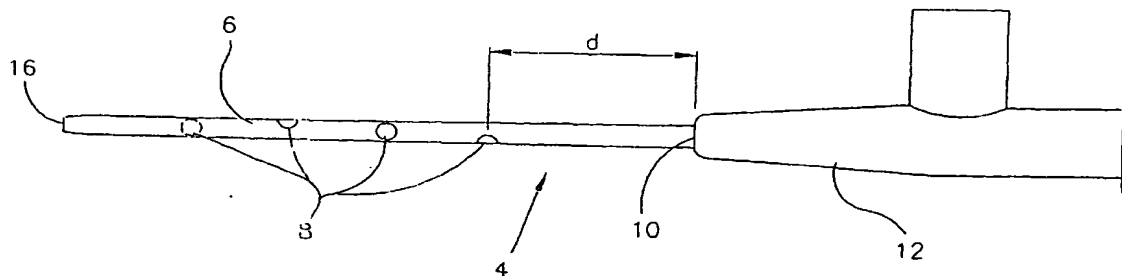
(19) World Intellectual Property Organization  
International Bureau(43) International Publication Date  
28 August 2003 (28.08.2003)

PCT

(10) International Publication Number  
WO 03/070309 A1

- (51) International Patent Classification<sup>7</sup>: A61M 25/00, 25/06
- (21) International Application Number: PCT/IT02/00097
- (22) International Filing Date: 19 February 2002 (19.02.2002)
- (25) Filing Language: Italian
- (26) Publication Language: English
- (71) Applicant (for all designated States except US): ANTEA ASSOCIAZIONE [—/IT]; Via Pienza, 281/283, I-00138 Rome (IT).
- (72) Inventor; and
- (75) Inventor/Applicant (for US only): TERZOLI, Leonardo [—/IT]; Via Diego Angeli, 95, I-00159 Rome (IT).
- (74) Agent: SARPI, Maurizio; Studio Ferrario, Via Collina, 36, I-00187 Rome (IT).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:  
— with international search report
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: IMPROVEMENT OF INTRA-VENOUS (I.V.) BLOOD CATHETER FOR SUBCUTANEOUS INFUSION OF LIQUIDS AND/OR DRUGS



(57) Abstract: Improvement of intra-venous (I.V.) catheters used for the subcutaneous administration of liquids or drugs comprising a introducer-needle (2) guiding a cannula or catheter made of flexible material, wherein said catheter (6) has, in addition to the ejection-hole (16) at the distal end, several additional holes (8), placed all over the lateral surface of said catheter. This enables to obtain a homogeneous and continuous diffusion of the infused liquid on a larger area of the patient's subcutis, avoiding formation of pomphus.

IMPROVEMENT OF INTRA-VENOUS (I.V.) BLOOD CATHETER FOR  
SUBCUTANEOUS INFUSION OF LIQUID AND/OR DRUGS.

The present invention relates to the field of  
medical-surgical devices and more particularly it  
concerns the improvement of intra-venous (I.V.)  
catheters used for subcutaneous administration of  
5 infusions and drugs.

Namely, an Intra-venous (I.V.) catheter is a  
device having an internal needle for the insertion of a  
catheter, consisting of an introducer-needle, usually  
made of steel, and an external cannula, preferably a  
10 teflon made tube having ultraslim walls that ensures  
the maximum flowability and flexibility and reduces  
trauma. After the tip of the needle, which protrudes  
from the distal end of the cannula, penetrates the  
patient's subcutaneous layer (under the derma), the  
15 operator removes the needle leaving the catheter in  
situ in order to connect said catheter to a syringe  
having no needle or any other infusion devices.

In the last years the technique of subcutaneously  
20 infusing liquids or drugs has become widespread  
probably because patients tolerate subcutaneous  
catheters better than endovenous catheters and, in  
addition, the use of subcutaneous catheters needs less  
precautions and they can easily used for domiciliary  
25 treatments.

However, traditional intra-venous (I.V.) catheters nowadays used, and commercially available, for subcutaneous administration of infusions and drugs are extremely sterilised, stable and reliable but they were  
5 conceived to be used but for a different utilisation: the endovenous administration.

People skilled in the field are aware that as above it can be a serious disadvantage, which can  
10 compromise the positive result of a therapy. We refer to the fact that no attention was paid on fluids dynamic, according to which the distal end of the catheter is the unique responsible for the downflow of administrated fluids.

15

Inevitably, when the catheter is subcutaneously inserted, real pomphus, macro-collection of liquid in localised areas of the patient's subcutis, appear and their size depends on the amount of the injected  
20 liquid.

This fact becomes really important in case of patients undergoing long-term administration, because frequently pomphus deriving from previous treatments  
25 can not be completely reabsorbed.

Object of the present invention is to overcome this disadvantage modifying traditional intra-venous (I.V.) catheters.

30

This was obtained, according to the invention, providing the catheter, in addition to the ejection-hole at the distal end, with supplementary holes, placed all over the catheter's surface.

5

Said holes ensure an homogeneous distribution of the injected liquid over a wider area of the subcutis, the extension of this area being directly proportional to the number of holes; in this manner formation of  
10 pomphus, as with traditional I.V. catheters, is avoided.

Further features and advantages of the invention will be more readily apparent from the following  
15 detailed description with reference to the accompanying drawings.

In the drawings:

Figure 1 shows the cannula having secondary holes placed all over the lateral surface;

20 Figure 2 shows the guide-needle, when it is drawn from the cannula;

Figure 3 shows the device of the present invention, ready to be use, with the needle inserted inside the cannula;

25 Figures 4a,4b and 5a,5b shows the results of a diffusion assay carried out on gauze where a liquid is infused using a traditional I.V. catheter and using the I.V. catheter of the present invention, at the time  $t_0$  and at the time  $t_1$  respectively;

30

With reference to the drawings, the I.V. catheter of the present invention, generically named as 4, does not differ, from commercially available I.V. catheters, as far as the materials used, the systems for the connection to the syringe and the systems for the infusion of the catheter, are concerned.

It substantially consists in an introducer-needle 2 having a sharp tip which ensures the maximum penetration index, said introducer-needle is inserted inside a cannula or catheter consisting of a small tube 6, preferably teflon-made, assembled on a usually plastic made (polypropylene or similar) support 12. For example, the length of the cannula is about 35-45 mm and its diameter is between 0,7 and 1,8 mm.

15

The innovative feature of the invention is that the catheter 6 is characterised in having, in addition to the main ejection-hole 16 at the distal end, several holes 8 placed all over the lateral surface.

20

Obviously, the distribution and the dimension of said holes 8 have to ensure the solidity of the cannula 6 and not compromise its mechanical resistance. Consequently, the holes are placed in order to result not aligned along the same generative line, but angularly spaced all over the lateral surface of the cannula.

As an example, the diameter of the holes is between 1,7 and 2,5 mm. It is important to underline

30

It is important to underline that, using the device of the present invention, a lower hydrostatic pressure is exerted in the cannula and it ensures a reduced localised traumatism.

5

Moreover, as focused in figure 2, the device was specifically designed for a subcutaneous use and not for an endovenous use and for this reason it is not necessary that the guide-needle is perforated. This  
10 feature, has a key role in the prevention of diseases which might be transmitted by human fluids, as HIV, because it removes the risk related to the use of perforated needles. In fact, inside the cavity of perforated needles potentially infected residues  
15 deriving from tissue and/or fluids might remain, maintaining their infectivity because they do not come in contact with external air.

## CLAIMS

1) Intra-venous (I.V.) catheter for the subcutaneous administration of drugs comprising an introducer-needle (2) and a cannula (6) inserted on a support (12) to be connected to a syringe or other infusion devices, wherein said cannula (6) has in addition to the main ejection-hole (16) at the distal end, several additional holes (8), placed all over its lateral surface.

10

2) Intra-venous (I.V.) catheter according to claim 1 wherein said additional holes (8) are suitably spaced and unaligned in order to ensure a distribution of the infused product on a wider area of the subcutis directly proportional to the number of holes, and in order to avoid formation of pomphus resulting from the administration with traditional I.V. catheter.

3) Intra-venous (I.V.) catheter according to claim 1 wherein the first additional hole (8) is made at a distance (d) from the dovetail (10) of the cannula on the support (12) where the syringe or an other infusion device is inserted, and this distance is sufficient to avoid discharge of the infused liquid from the hole for the insertion of the needle in the skin, in a backward manner.

4) Intra-venous (I.V.) catheter according to the previous claims wherein the section of each additional

hole (8) is smaller than the section of the main ejection-hole (16) at the distal end.

5        5)    Intra-venous (I.V.) catheter according to the previous claims wherein the section of additional holes (8) increases toward the distal end of the cannula.

6)    Intra-venous (I.V.) catheter according to the previous claims wherein the introducer-needle (2) is  
10    not perforated.

7)    Intra-venous (I.V.) catheter according to the previous claims wherein the cannula (6) is made of plastic material opaque to radiations.

15

8        Intra-venous (I.V.) catheter according to the previous claims wherein the cannula (6) is made of transparent and flexible plastic material.



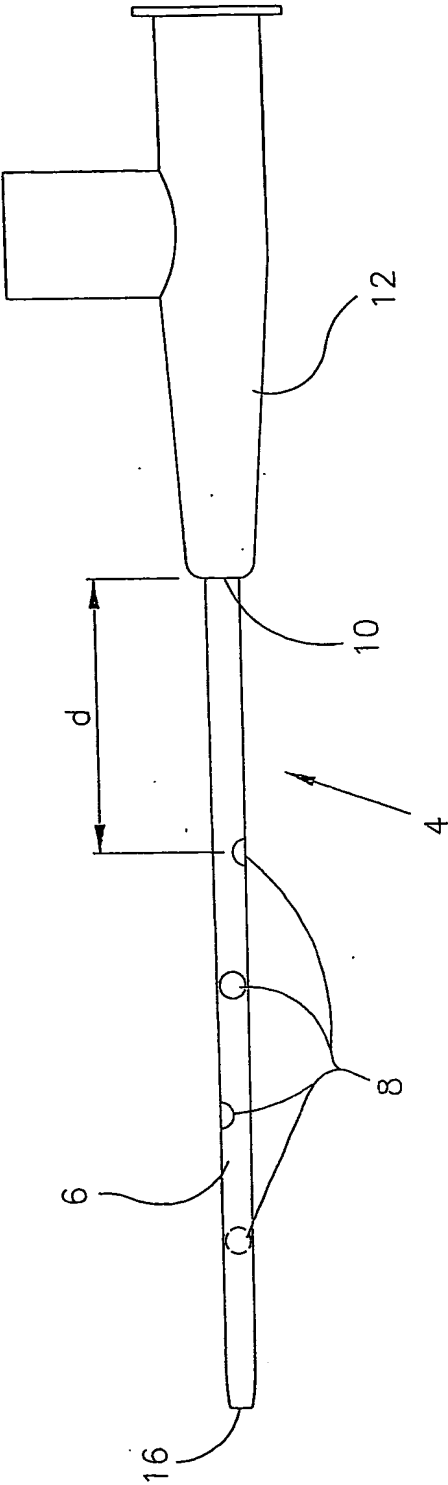


FIG. 1

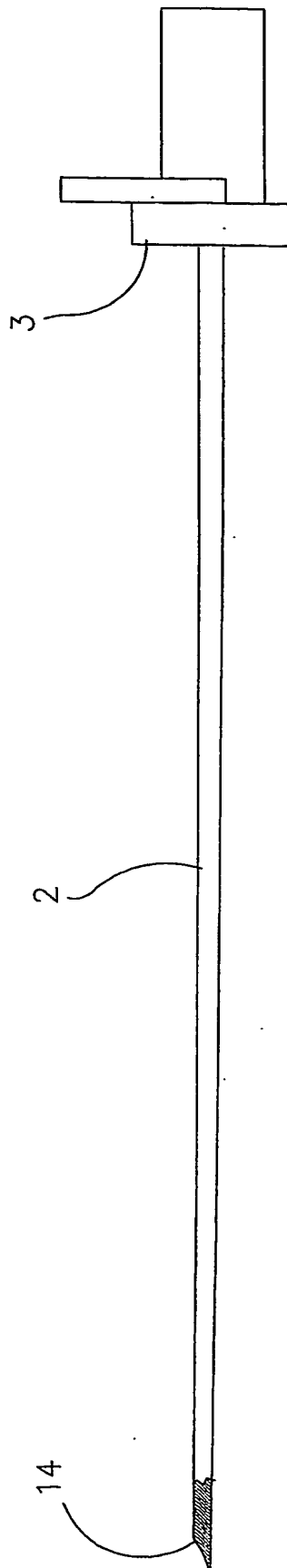


FIG. 2

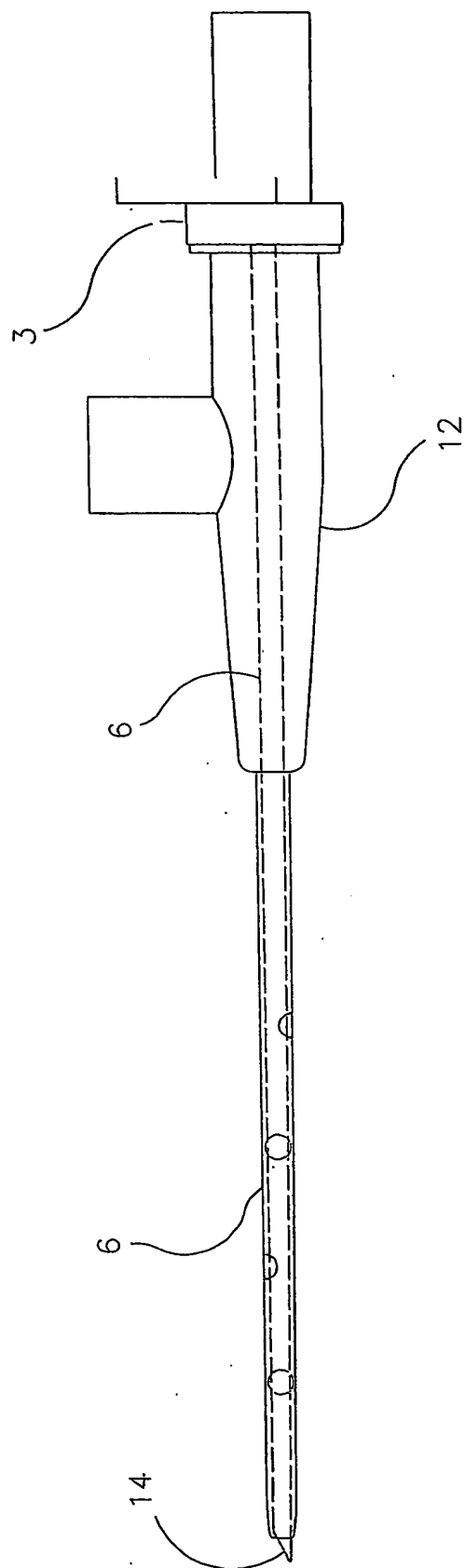


FIG. 3

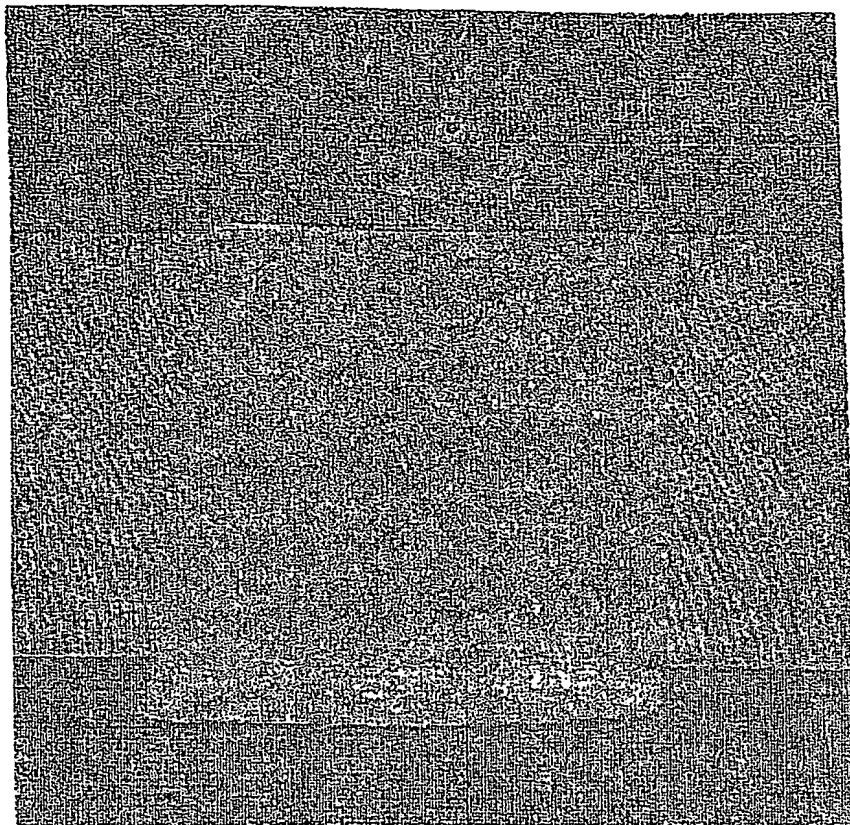


FIG. 4A

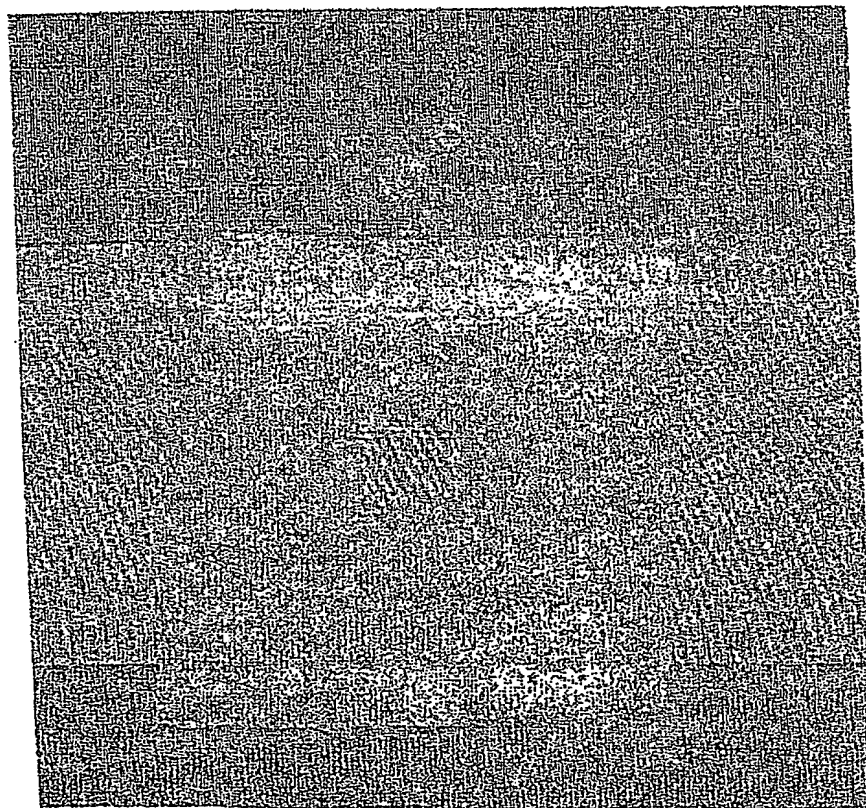


FIG. 4B

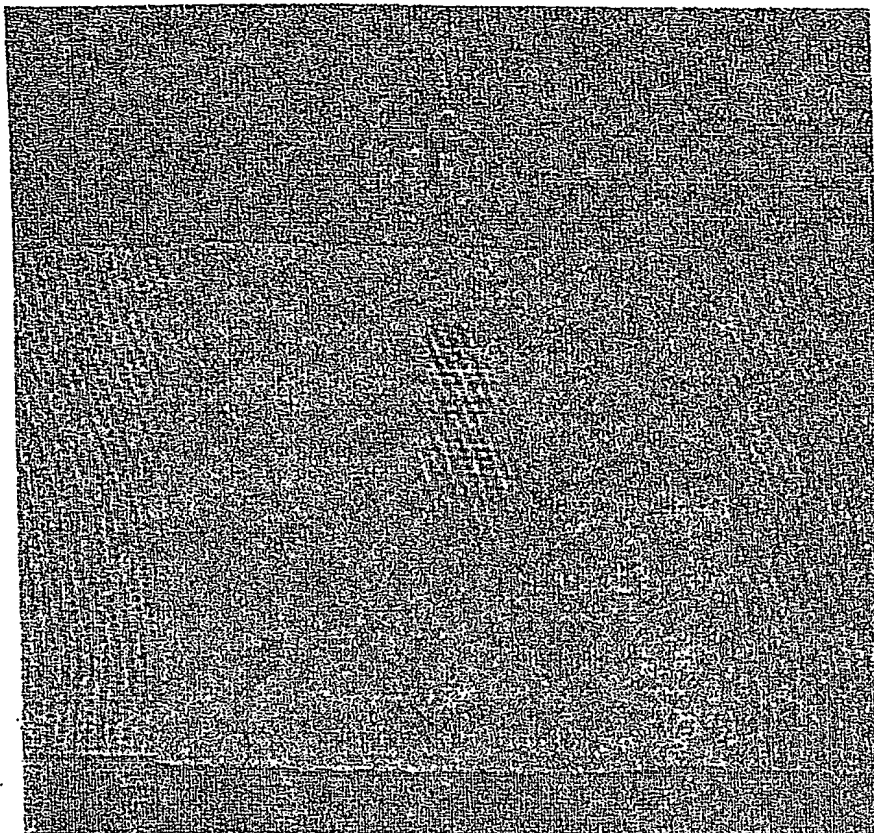


FIG. 5A

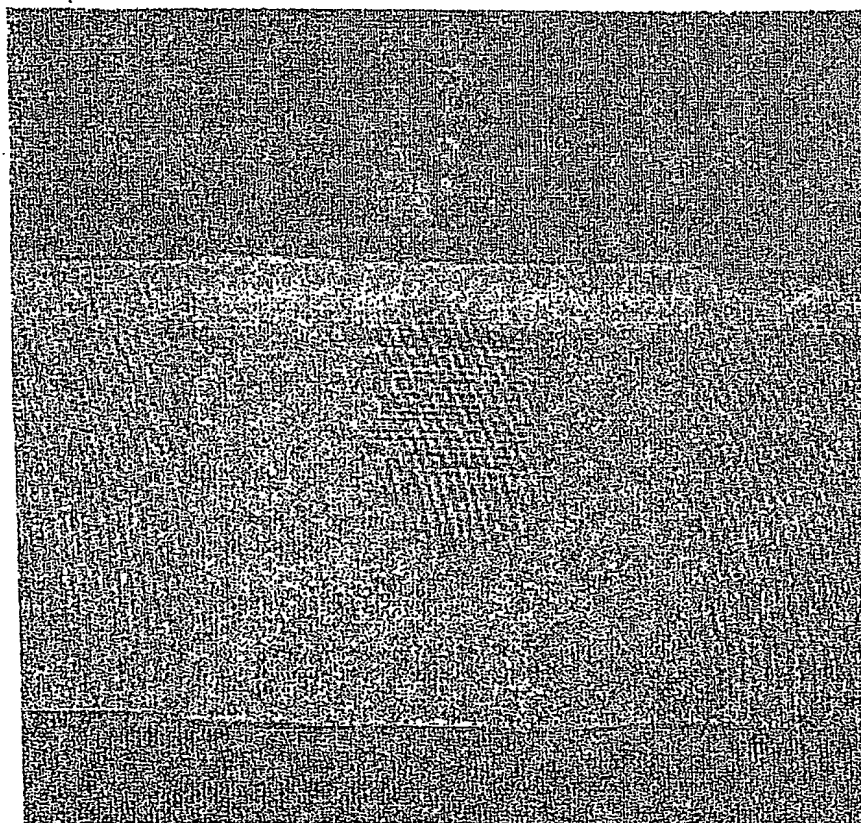


FIG. 5B

BEST AVAILABLE COPY

## INTERNATIONAL SEARCH REPORT

 International Application No  
 PCT/IB/00097

 A. CLASSIFICATION OF SUBJECT MATTER  
 IPC 7 A61M25/00 A61M25/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 078 689 A (KELLER ALAN M) 7 January 1992 (1992-01-07) column 2, line 14 -column 3, line 13; figures ---	1,3,6-8
X	EP 0 411 605 A (TERUMO CORP) 6 February 1991 (1991-02-06) column 7, line 3 -column 10, line 13; figures ---	1,3
X	US 5 505 710 A (DORSEY III JAMES H) 9 April 1996 (1996-04-09) column 6, line 16 - line 37; figures ---	1,3,4
A	GB 1 458 483 A (BURRI C KINZL L MUELLER A;WOLTER D) 15 December 1976 (1976-12-15) page 2, line 23 - line 37; figures --- -/--	1,3-5

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \* & \* document member of the same patent family

Date of the actual completion of the international search

27 January 2003

Date of mailing of the international search report

03/02/2003

Name and mailing address of the ISA

 European Patent Office, P.B. 5818 Patentlaan 2  
 NL - 2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax (+31-70) 340-3016

Authorized officer

Kousouretas, I

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/IB 2/00097

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 804 936 A (COOK INC) 5 November 1997 (1997-11-05) page 4, line 20 - line 53; figures ---	1,3-5,7, 8
A	US 6 197 014 B1 (DOAN HANH ET AL) 6 March 2001 (2001-03-06) column 13, line 45 -column 14, line 6; figures 11,12 ---	1-5,7,8
A	US 6 063 069 A (CRAGG ANDREW H ET AL) 16 May 2000 (2000-05-16) abstract; figures -----	1-3

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/ISA/2/00097

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5078689	A	07-01-1992	NONE	
EP 0411605	A	06-02-1991	JP 3066379 A	22-03-1991
			JP 2510886 B2	26-06-1996
			JP 3092170 A	17-04-1991
			AU 623031 B2	30-04-1992
			AU 6012690 A	07-03-1991
			DE 69019886 D1	13-07-1995
			DE 69019886 T2	16-11-1995
			EP 0411605 A1	06-02-1991
US 5505710	A	09-04-1996	NONE	
GB 1458483	A	15-12-1976	DE 2400117 A1	31-07-1975
			BE 824080 A1	02-05-1975
			CH 579926 A5	30-09-1976
			DD 116142 A5	12-11-1975
			DK 681774 A	08-09-1975
			FR 2256769 A1	01-08-1975
			NL 7417047 A ,B,	07-07-1975
			SE 399518 B	20-02-1978
			SE 7416337 A	04-07-1975
EP 0804936	A	05-11-1997	US 6117125 A	12-09-2000
			EP 0804936 A2	05-11-1997
			JP 10043302 A	17-02-1998
US 6197014	B1	06-03-2001	US 5782811 A	21-07-1998
			AU 692733 B2	11-06-1998
			AU 2359297 A	08-01-1998
			CA 2206367 A1	30-11-1997
			EP 0810003 A2	03-12-1997
			JP 2965940 B2	18-10-1999
			JP 10071208 A	17-03-1998
			NO 972452 A	01-12-1997
US 6063069	A	16-05-2000	CA 2238064 A1	19-11-1998
			EP 0879578 A1	25-11-1998



CORRECTED VERSION

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
28 August 2003 (28.08.2003)

PCT

(10) International Publication Number  
WO 2003/070309 A1

(51) International Patent Classification<sup>7</sup>: A61M 25/00,  
25/06

GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,  
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,  
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,  
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,  
VN, YU, ZA, ZM, ZW.

(21) International Application Number:  
PCT/IT2002/000097

(22) International Filing Date: 19 February 2002 (19.02.2002)

(84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,  
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent  
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,  
NE, SN, TD, TG).

(25) Filing Language: Italian

(26) Publication Language: English

(71) Applicant (*for all designated States except US*): ANTEA  
ASSOCIAZIONE [—/IT]; Via Pienza, 281/283, I-00138  
Rome (IT).

Published:  
— with international search report

(71) Applicant and

(72) Inventor: TERZOLI, Leonardo [—/IT]; Via Diego An-  
geli, 95, I-00159 Rome (IT).

(48) Date of publication of this corrected version:  
27 January 2005

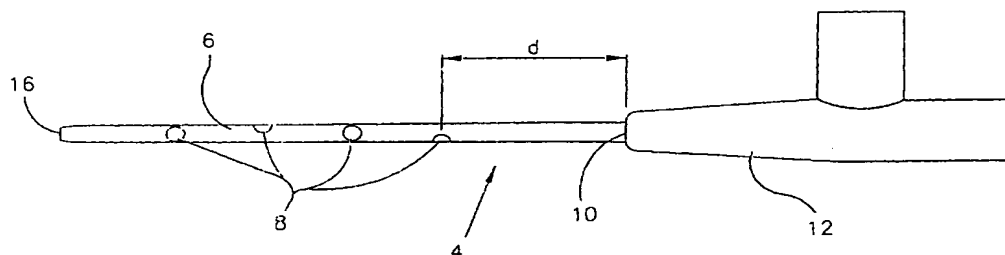
(74) Agent: SARPI, Maurizio; Studio Ferrario, Via Collina,  
36, I-00187 Rome (IT).

(15) Information about Correction:  
see PCT Gazette No. 04/2005 of 27 January 2005, Sec-  
tion II

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,

*For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.*

(54) Title: IMPROVEMENT OF INTRA-VENOUS (I.V.) BLOOD CATHETER FOR SUBCUTANEOUS INFUSION OF LIQ-  
UIDS AND/OR DRUGS



(57) Abstract: Improvement of intra-venous (I.V.) catheters used for the subcutaneous administration of liquids or drugs comprising a introducer-needle (2) guiding a cannula or catheter made of flexible material, wherein said catheter (6) has, in addition to the ejection-hole (16) at the distal end, several additional holes (8), placed all over the lateral surface of said catheter. This enables to obtain a homogeneous and continuous diffusion of the infused liquid on a larger area of the patient's subcutis, avoiding formation of pomphus.

WO 2003/070309 A1